

**Remarks**

Claims 1-16, 18-23, 25, and 50-58, are pending in the application.

With this amendment, claims 1, 9, 18, 25, 50, 51, 52, 53, 54, 55, and 58 have been amended and claims 59-68 are added. Claims 10-16 are presently cancelled.

Claims 1-9, 18-23, 25, 50-68, remain in the application for consideration.

No additional fee is believed to be required for filing this response. However, if any additional fee is required, please charge all of the appropriate fee to the Kagan Binder Deposit Account No. 50-1775 and notify us of the same.

Reconsideration and allowance of the claims as amended and in light of the following remarks, are respectfully requested.

Support for the amended and new claims can be found in the specification as originally filed, for example as follows:

Support for the feature of an in vivo lifetime of at least two weeks, as recited in claims 1, 25, and others, can be found at original claim 50 and in the specification as originally filed, e.g., at published paragraph 0048 and figures 8 and 9.

Support for the range of 50 kGy to 75 kGy gamma irradiation, as recited in amended claim 9 and in new claims 59, 61, and 64, can be found, e.g., in the original claims and at published paragraphs 0047 and 0048, and related figures.

Support for the feature of “molded or cut openings” of amended claims 18 and 25 can be found at published paragraph 0050.

Support for amended claim 50 can be found, e.g., at published paragraph 0048 and at figures 8 and 9.

Support for new claim 60 is found, e.g., by braided embodiments and “fenestrated” embodiments, e.g., at paragraphs 0012, 0013, figures 1A, 1B, 1C, and 3, and at original claim 50 and its related specification.

Support for new claims 62, 63, 65, 66, 67, and 68 can be found, e.g., at published paragraphs 38-42 and at figures 4-7.

### **Claim Rejections - 35 U.S.C. 103**

#### **Claim 25**

Claim 25 is rejected under 35 U.S.C. 103(a) over Hogan (U.S. Patent No. 6,569,191; referred to herein as “Hogan”) in view of Stack et al. (International Publication No. WO 91/17789; referred to herein as “Stack”).

Amended claim 25 recites a stent comprising a tubular sheath, a fenestrated walled surface comprising molded or cut openings, said fenestrated walled surface comprised of polydioxanone, wherein said tubular sheath is annealed and exhibits an in vivo lifetime of at least 2 weeks.

The cited prior art has not been shown to suggest this combination of features in a stent, and the rejection of claim 25 can be withdrawn.

#### **Claims 1-3, 8-11, 16, 18-23, 50, 51 and 57**

Claims 1-3, 8-11, 16, 18-23, 50, 51 and 57 stand rejected under 35 U.S.C. 103(a) over Hogan in view Stack and Cotterman et al. (U.S. Patent Application No. 2002/0153511; herein referred to “Cotterman”).

The rejection of these claims is overcome by amendment to claims 1, 18, and 51.

Claims 1 and 51 have been amended to recite a bioresorbable stent that has been annealed and also exposed to at least 35 kGy of gamma irradiation, and that still exhibits an in vivo lifetime of at least 2 weeks.

According to the application at published paragraph 0012, a in vivo functional lifetime is:

the minimum length of time that the implanted stent would maintain adequate physical integrity and strength to maintain patency of a constricted region of a body lumen.

The cited references, either alone or in combination, have not been shown to teach or suggest a bioresorbable stent that has been both annealed and exposed to at least 35 kGy of gamma irradiation, and that still exhibits adequate physical integrity and strength to maintain patency of a constricted region of a body lumen for at least 2 weeks.

The Hogan reference fails to describe either annealing or gamma irradiation treatment of a polymeric bioresorbable stent.

The Stack reference is cited for describing annealing.

The Cotterman et al. reference is cited for describing gamma irradiation of medical devices generally, for sterilization.

The cited combination of references has not been shown to suggest that a bioresorbable polymeric stent can be annealed, and irradiated with at least 35 kGy of gamma irradiation, and can still exhibit an in vivo lifetime of at least 2 weeks. This combination of features of a bioresorbable stent is not suggested by the cited prior art references, and the claimed combination would not have been obvious over this combination of references.

Features of claims dependent from claim 1 are further patentable. For example, claim 9, which is presently amended to depend from claim 1, recites a stent irradiated with from 50 to 75 kGy gamma irradiation.

The rejections of claims 1 and 51, and their dependent claims, can be withdrawn, in view of the amendments to claims 1 and 51.

Regarding claim 18 and its dependent claims, the cited combination of Hogan, Stack, and Cotterman et al. also has not been shown to teach or suggest the subject matter of amended claim 18 and its dependent claims, reciting a bioresorbable polymeric, gamma-irradiated stent comprising molded or cut openings, as claimed.

Claims 52 through 55, dependent from claim 1, are rejected further in combination with the Shaolian et al. reference, which is cited as describing certain expansion forces. The rejection is overcome by amendments to claims 1 and 52 through 55. The Shaolian et al. reference has not been shown to discuss bioresorbable, urethral stents having the specific in vivo lifetime and strength features recited in claims 52 through 55. The rejection based on cited combination of references, therefore, is overcome and can be withdrawn.

Added claims 59 through 68 are believed to also be patentable. These claims include features that, in combination, are believed to be novel and non-obvious. Exemplary claims feature one or more of:

a bioresorbable polymeric stent that is annealed and gamma irradiated in the range from 50 to 75 kGy;

an annealed and gamma-irradiated (35 to 75 kGy) bioresorbable polymeric stent having in vivo lifetime of at least two weeks;

gamma irradiated, bioresorbable, polymeric urethral stents that exhibit specific expansion and radial forces.

In view of the present amendments and remarks, Applicants submit that the outstanding rejections have been either overcome or should otherwise be withdrawn. Reconsideration of the claims as amended, and allowance of the pending claims, are respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

By:



Daniel C. Schulte, Reg. # 40,160

**Customer Number 33072**

Phone: 651-275-9806

Facsimile: 651-351-2954

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